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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/590,477

08/24/2006

Amir Barzilay

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7590

07/08/2009

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EXAMINER

HELLING, KAITLYN ELIZABETH

ART UNIT

PAPER NUMBER

3739

MAIL DATE

DELIVERY MODE

07/08/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/590,477	<b>Applicant(s)</b> BARZILAY ET AL.	
	<b>Examiner</b> KAITLYN E. HELLING	<b>Art Unit</b> 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 13 May 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-7, 16, 18, 19, 25-28, 37, 39, 48, 54 and 70 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-7, 16, 18, 19, 25-28, 37, 39, 48, 54 and 70 is/are rejected.
- 7) ☐ Claim(s) 8, 12, 17, 33 and 38 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>08/24/2006 and 05/13/2009</u> .                               | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 4, 5 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4, 5 and 6 recites the limitation "said wave condenser" in the second line of the claim. There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 3, 7, 16, 18, 25, 37, 39 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2005/0154332 A1 to Zanelli et al. (Zanelli) in view of US 6,544,259 B1 to Tsaliovich (Tsaliovich).

Regarding claims 1, 3 and 25 Zanelli teaches methods and systems for removing hair using focused acoustic energy (title), comprising transmitting acoustic waves to heat at a follicle, a dermal papilla, a hair bulge and/or a germinal matrix of the hair ([0019], pg. 2) said heat being in itself sufficient to damage or destroy said follicle, said dermal papilla, said hair bulge and/or said germinal matrix ([0002] and [0010], pg. 1)

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using an appropriately focused transducer (10). However, Zanelli does not specifically disclose transmitting the acoustic waves through the hair via a wave condenser gripping configuration. Tsaliovich teaches a hair removal method and device (title) which uses radiofrequency in conjunction with the application of ultrasonic waves through the tweezers tips (17 and here interpreted as a wave condenser) of the device (20) which allows for the application of the ultrasonic energy through the hair itself (Figs. 1a-1c). It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified Zanelli to have included the direct application of the ultrasonic waves of Tsaliovich in order to reduce the attenuation of the ultrasonic waves to enhance the propagation of the waves/the acoustic coupling as it is well known in the art that the propagation of ultrasonic waves through the air attenuates the waves and reduces their efficiency.

Regarding claim 7, Zanelli in view of Tsaliovich teaches the method of claim 3 with Tsaliovich teaching the further limitation of pulling the hair so as to effect detachment of the hair (abstract). It would have been obvious to one having ordinary skill in the art at the time of the invention to have included the modality of pulling the hair out as taught by Tsaliovich in order to remove the slackened hair from the body (Col. 3, lines 1-12).

Regarding claims 16 and 18, Zanelli in view of Tsaliovich teaches the method of claim 1 with Zanelli teaching the further limitation of wherein at least one of a frequency, a power density and duration of transmission ([0010], pg. 1) of said acoustic waves is selected such that said generation of said heat is such that said heat results in a

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temperature increment of at least 20 degrees centigrade ([0010], pg. 1) and that the acoustic waves comprise ultrasound waves ([0008], pg. 1).

Regarding claim 37, Zanelli in view of Tsaliovich teaches the device of claim 25, with Zanelli teaching the further limitation of wherein at least one of a frequency, a power density and duration of transmission ([0010], pg. 1) of said acoustic waves is selected such that said generation of said heat is such that said heat results in a temperature increment of at least 20 degrees centigrade ([0010], pg. 1).

Regarding claim 39, Zanelli in view of Tsaliovich teaches the device of claim 37, with Zanelli teaching the further limitation of wherein the acoustic waves comprise ultrasound waves ([0008], pg. 1).

Regarding claim 54, Zanelli in view of Tsaliovich teaches the device of claim 39 with Tsaliovich teaching the wave condenser comprising a chamber configured to receive the hair (Figs. 1a and 1b and Col. 4, lines 13-18). It would have been obvious to one having ordinary skill in the art at the time of the invention to have included the wave condenser comprising a chamber for receiving the hair as taught by Tsaliovich as Tsaliovich teaches that this aids in the removal of the hair and allows the ultrasound waves to be applied through the tweezers.

5. Claims 2, 4-6, 19, 26-28 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zanelli and Tsaliovich as applied to claims 1 and 3 above, and further in view of Masotti (Masotti).

Regarding claim 2, Zanelli in view of Tsaliovich teaches the method of claim 1, but not the inclusion of a wave condenser for condensing the acoustic waves prior to

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transmitting the acoustic waves through the hair. Masotti teaches a method and device for epilation by ultrasound (title) which uses a condenser to focus the acoustic waves prior to their transmission through the hair (pg. 3, lines 30-pg. 4, lines 14 and pg. 8, lines 3-10). It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified Zanelli in view of Tsaliovich with the wave condenser of Masotti as Masotti teaches that focusing the waves prior to application to the hair which achieves the result of arranging the ultrasonic waves at a suitable selected depth in order to make the diameter of the focused waves as small as possible allowing for a high density of energy to be carried by the waves and to strike only the desired target (pg. 4, lines 8-14).

Regarding claims 4-6, Zanelli in view of Tsaliovich teaches the method of claim 3, but not a wave condenser or the propagation direction of the acoustic waves being generally parallel, perpendicular or inclined to a longitudinal axis of the hair. Masotti teaches a method and device for epilation by ultrasound (title) which uses a condenser to focus the acoustic waves prior to their transmission through the hair (pg. 3, lines 30-pg. 4, lines 14 and pg. 8, lines 3-10). It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified Zanelli in view of Tsaliovich with the wave condenser of Masotti as Masotti teaches that focusing the waves prior to application to the hair which achieves the result of arranging the ultrasonic waves at a suitable selected depth in order to make the diameter of the focused waves as small as possible allowing for a high density of energy to be carried by the waves and to strike only the desired target (pg. 4, lines 8-14).

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With respect to the propagation directions, in light of the lack of any disclosed criticality of the propagation direction of the acoustic waves with respect to the longitudinal axis of the hair, it would have been obvious to one having ordinary skill in the art at the time of the invention to have modified Zanelli, Tsaliovich and Masotti to have selected a desired propagation direction as an obvious matter of design choice to achieve the desired result of removing the hair.

Regarding claim 19, Zanelli in view of Tsaliovich teaches the method of claim 16, but not that the ultrasound waves are at a frequency of at least 150 kHz. Masotti teaches that the use of ultrasound frequencies in the range from a few hundred kHz to a few MHz, and typically from 100 kHz to 10 MHz makes it possible to obtain a focal spot with lateral dimensions which may be up to a few tenths of the millimeter and a longitudinal extension which may be a few millimeters (pg. 5, lines 16-19) this allows the volume affected by the raising of the temperature to be small. Thus the necrosis of the follicle can be achieved with minimal damage, or none at all, to the surrounding tissues (pg. 5, lines 21-23). While Masotti does not specifically teach the frequency of at least 150 kHz, it has been held that where the general conditions of the claims are met, it is not patentable to discover the optimal range through routine experimentation (see MPEP 2144.05).

Regarding claims 26-28, Zanelli in view of Tsaliovich teaches the device of claim 25, but not the propagation directions of the acoustic waves. However, in light of the lack of any disclosed criticality of the propagation direction of the acoustic waves with respect to the longitudinal axis of the hair, it would have been obvious to one having

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ordinary skill in the art at the time of the invention to have modified Zanelli, Tsaliovich and Masotti to have selected a desired propagation direction as an obvious matter of design choice to achieve the desired result of removing the hair.

Regarding claim 48, Zanelli in view of Tsaliovich teaches the device of claim 25, but not a focusing element coupling the transducer and the wave condenser in order to focus the acoustic waves into the wave condenser. However, Masotti teaches the use of a focusing element either using an intrinsically focused plate, acoustic lenses between the treatment area and the transducer or electronic focusing (Col. 4, lines 1-4). It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified Zanelli and Tsaliovich to have included the focusing element of Masotti between the transducer and the wave condenser as Masotti teaches that focusing the ultrasonic energy results in making the beam converge toward an area of space located at a certain desired distance from the interface between the ultrasonic transducer and the propagation medium of the ultrasonic waves (Col. 4, lines 4-7).

Regarding claim 70, Zanelli in view of Tsaliovich teaches the device of claim 39 with Masotti teaching that the use of ultrasound frequencies in the range from a few hundred kHz to a few MHz, and typically from 100 kHz to 10 MHz makes it possible to obtain a focal spot with lateral dimensions which may be up to a few tenths of the millimeter and a longitudinal extension which may be a few millimeters (pg. 5, lines 16-19) this allows the volume affected by the raising of the temperature to be small. Thus the necrosis of the follicle can be achieved with minimal damage, or none at all, to the surrounding tissues (pg. 5, lines 21-23). While Masotti does not specifically teach the



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frequency of at least 150 kHz, it has been held that where the general conditions of the claims are met, it is not patentable to discover the optimal range through routine experimentation (see MPEP 2144.05).

***Allowable Subject Matter***

6. Claims 8, 12, 17, 33 and 38 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art of record does not teach or fairly suggest the acoustic coupling being characterized by selecting a coupling length thus resulting in a temperature increment of at least 20 degrees, that at least one of a frequency, a power density and duration of transmission is selected in order to minimize vibrations of the hair or that the frequency is advantageously off-resonance. The prior art does not suggest that there is any criticality to the coupling length and its effect on the resultant temperature increment. Also, with respect to the minimization of the vibrations, the prior art generally suggests that the vibrations are wanted in order to loosen the hair and therefore do not suggest a minimization of the vibrations. Applicant has disclosed that these large vibrations weaken the hair shaft and reduce its ability to effectively transmit waves to the hair root. This criticality of low frequency vibrations as being beneficial to the transmission of the waves to the hair root is not contemplated by the prior art.

***Conclusion***

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 2003/0212351 A1 teaches methods of using high frequency focused ultrasound to form an ablated tissue area containing a plurality of lesions..

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAITLYN E. HELLING whose telephone number is (571)270-5845. The examiner can normally be reached on Monday - Friday 9:00 a.m. to 5:30 p.m. EDT.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571)272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

9. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KAITLYN E. HELLING/

/Roy D. Gibson/

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Examiner, Art Unit 3739

Primary Examiner, Art Unit 3739